

IN THE CLAIMS:

1. (Currently Amended) Process for the gentle preparation of superfine micro- and nanoparticles having a particle size, as average diameter of the number distribution, of 5.6  $\mu\text{m}$  or less, the method comprising:

subjecting a matrix material comprising solid particles to a high-pressure homogenizing process in a piston-gap homogenizer in an anhydrous or water-reduced dispersion medium containing less than 50 wt.% of water in which the solid particles are suspended and at temperatures of below 20°C or less, which leads to a gentle particle size reduction with minimization of the impairment of the chemical stability of the homogenized material, to form superfine micro- and nanoparticles.
2. (Previously Presented) Process according to claim 1, wherein the homogenized matrix material comprises at least one selected from the group consisting of drugs, pharmaceutical active ingredients, veterinary drugs, active ingredients, auxiliaries, additives for cosmetics, agricultural products, foodstuffs and preservatives.
3. (Previously Presented) Process according to claim 2, wherein the homogenized matrix material comprises at least one drug selected from the group consisting of ciclosporin, azodicarbonamide, paclitaxel, prednisolone, carbamazepine, taxol, morphine, diclofenac, ibuprofen, phenobarbital and cromoglycin.
4. (Previously Presented) Process according to claim 1, wherein the homogenized matrix material comprises at least one selected from the group consisting of synthetic, semi-synthetic or natural polymers, and natural macromolecules.
5. (Previously Presented) Process according to claim 4, wherein the

- homogenized matrix material comprises at least one selected from the group consisting of synthetic polymers, polylactide, polyglycolide, polylactide/-glycolide co-polymer, polyorthoester, polyhydroxybutyrate (PHB), polyhydroxyvalerate (PHV), polyhydroxybutyrate/-valeriate co-polymer, polyacrylates, polymethacrylates, polyvinyl derivatives, block polymers of polyethylene glycol and polyesters, polyhydroxybutyric acid, polycyanoacrylates, polycarbonates and polycaprolacton.
6. (Previously Presented) Process according to claim 4, wherein the homogenized matrix material comprises at least one selected from the group consisting of natural macromolecules, alginates, albumin, serum albumin, human albumin, bovine albumin, collagen, casein, fibrin, tragacanth, xanthans, polysaccharides, chitin, dextrans and hyaluronic acid.
  7. (Previously Presented) Process according to claim 1, wherein the homogenized matrix material comprises polymers or natural macromolecules loaded with drugs or active ingredients.
  8. (Previously Presented) Process according to claim 7, wherein the homogenized matrix material comprises at least one polymer selected from the group consisting of polylactide, polyglycolide, polylactide/-glycolide co-polymer, polyorthoester, polyhydroxybutyrate (PHB), polyhydroxyvalerate (PHV), and polyhydroxybutyrate/-valeriate co-polymer.
  9. (Previously Presented) Process according to claim 7, wherein the homogenized matrix material comprises at least one selected from the group consisting of natural macromolecules, in particular alginates, albumin, preferably serum albumin, human albumin and bovine albumin, collagen, casein, fibrin, bentonite, tragacanth, xanthans, polysaccharides such as chitin, dextrans and hyaluronic acid.
  10. (Previously Presented) Process according to claim 1, wherein the materials to

- be reduced in size are dispersed in a non-aqueous dispersion medium.
11. (Previously Presented) Process according to claim 10, wherein the materials to be reduced are dispersed in an oily medium.
  12. (Previously Presented) Process according to claim 10, wherein the materials to be reduced are dispersed in liquid hydrocarbons.
  13. (Previously Presented) Process according to claim 10, wherein the materials to be reduced are dispersed in at least one selected from the group consisting of polyethylene glycols (PEGs), PEG 100 to PEG 1000, anhydrous glycerol, anhydrous alcohols, methanol, ethanol, 1-propanol, isopropanol, n-butanol, 2-butanol, pentanol, hexanol, octanol, decanol, allyl alcohol, propargyl alcohol, ethanol, isopropanol butanol, and propylene glycols.
  14. (Previously Presented) Process according to claim 10, characterized in that the materials to be reduced are dispersed in dimethyl sulfoxide.
  15. (Previously Presented) Process according to claim 1, wherein the materials to be reduced are dispersed in a dispersion medium that contains a small or minimized proportion or proportion desired, for product-related reasons, of water.
  16. (Previously Presented) Process according to claim 15, wherein the materials to be reduced are dispersed in a dispersion medium containing less than 5 wt.-% water.
  17. (Previously Presented) Process according to claim 15, wherein the materials to be reduced are dispersed in a dispersion medium which contains less than 10 wt.-% water.
  18. (Cancelled)

19. (Cancelled)
20. (Previously Presented) Process according to claim 15, wherein the materials to be reduced are dispersed in a dispersion medium comprising water and at least one dissolved substance selected from the group consisting of polymers, polyethylene glycols solid at room temperature, PEG 6000, cellulose derivatives, and hydroxypropyl methylcellulose (HPMC).
21. (Cancelled)
22. (Cancelled)
23. (Cancelled)
24. (Previously Presented) Process according to claim 1, wherein the process temperature is below the freezing point of water.
25. (Previously Presented) Process according to claim 1, wherein the process is carried out with the exclusion of oxygen.
26. (Previously Presented) Process according to claim 1, further comprising degassing the dispersion medium before use.
27. (Currently Amended) Superfine micro- or nanoparticle dispersions having a particle size, as average diameter of the number distribution, of 5.6  $\mu\text{m}$  or less, prepared according to a process comprising:  
subjecting a matrix material to a high-pressure homogenizing process in a piston-gap homogenizer in an anhydrous or water-reduced medium containing less than 50 wt.% of water and/or at low temperatures below of 20 °C or less, which leads to a gentle particle size reduction with minimization of the impairment of the chemical stability of the homogenized material and

- forms a dispersion comprising the superfine micro- or nanoparticles.
- 28. (Previously Presented) Process according to claim 1, wherein the particle size is less than 5 µm.
  - 29. (Previously Presented) Process according to claim 1, wherein the particle size is less than 1 µm.
  - 30. (Cancelled)
  - 31. (Previously Presented) Process according to claim 1, wherein the homogenization process is conducted at temperatures below the freezing point of water.
  - 32. (Previously Presented) Process according to claim 11, wherein the oily medium comprises at least one selected from the group consisting of medium chain triglycerides (MCT), peanut oil, avocado oil, cottonseed oil, safflower oil, long chain triglycerides (LCT), in particular soybean oil, triacetin and isopropyl myristate.
  - 33. (Previously Presented) Process according to claim 12, wherein the liquid hydrocarbon comprises at least one selected from the group consisting of fluid paraffin, viscous paraffin, hexane and octane.
  - 34. (Previously Presented) Process according to claim 16, wherein the dispersion medium contains less than 1 wt.-% of water.

Claims 35-37 (Cancelled)

- 38. (Previously Presented) Process according to claim 1, wherein the process temperature is 4 °C.

39. (Previously Presented) Process according to claim 24, wherein the process temperature is below -20 °C.
40. (Previously Presented) Process according to claim 24, wherein the process temperature is below -50 °C.
41. (Previously Presented) Process according to claim 25, further comprising gassing the matrix material and medium with inert gases.
42. (Previously Presented) Process according to claim 41, wherein the inert gas comprises at least one selected from the group consisting of nitrogen and argon.
43. (Previously Presented) Process according to claim 25, wherein the homogenization process is conducted under a vacuum.
44. (Previously Presented) Process according to claim 1, wherein the homogenizing process is conducted in a piston-gap homogenizer in an anhydrous medium.
45. (Previously Presented) Process according to claim 27, wherein the homogenizing process is conducted in a piston-gap homogenizer in an anhydrous medium.
46. (Previously Presented) Process for the gentle preparation of superfine micro- and nanoparticles having a particle size, as average diameter of the number distribution, of 5.6 μm or less, the method comprising:
  - dispersing solid particles in an anhydrous or water-reduced dispersion medium containing less than 50 wt.% of water to form a pre-suspension; and
  - subjecting the pre-suspension to a high-pressure homogenizing process in a piston-gap homogenizer to reduce the particle size without

cavitation with minimization of the impairment of the chemical stability of the homogenized material, to form superfine micro- and nanoparticles.

47. (Previously Presented) Process for the gentle preparation of superfine micro- and nanoparticles having a particle size, as average diameter of the number distribution, of 5.6  $\mu\text{m}$  or less, the method comprising:

dispersing solid particles comprising a drug, pharmaceutical active ingredient, or veterinary drug in an anhydrous or water-reduced dispersion medium containing less than 50 wt.% of water to form a pre-suspension; and

subjecting the pre-suspension to a high-pressure homogenizing process in a piston-gap homogenizer to reduce the particle size without cavitation with minimization of the impairment of the chemical stability of the homogenized material, to form superfine micro- and nanoparticles comprising the drug, pharmaceutical active ingredient, or veterinary drug.